REMARKS

Claims 1-6 and 8-16 are pending in the application and stand finally rejected. In the final office action mailed December 29, 2005, the Examiner has not accepted Applicants' allegation of criticality because in the Examiner's view, the allegation is unsupported by evidence of record. Applicants respectfully disagree with the Examiner's position. At the outset, Applicants have not alleged "criticality." That is the Examiner's term. Also, the Applicants have amended claim 1 to recite that the bioactive agent is homogenously distributed within the polymer fiber. Support for the amendment is found at page 2 lines 31-33.

Applicants have argued that the Examiner's combination of Vacanti et al., U.S. Patent No. 6,348,069, in view of Martin et al., U.S. Patent No. 6,162,537 fails to teach or suggest the affirmative method step of incorporating bioactive agent into polymer fibers during fiber formation by mixing an aqueous solution of the bioactive agent to the polymer solution to form an emulsion. The Examiner has not disputed that both references fail to teach using an emulsion technique to introduce bioactive agents into a polymer fiber during fiber formation. The Examiner has certainly not identified any column or line citation where the references disclose an emulsion, let alone an emulsion formed from an aqueous solution of a bioactive agent and a polymer solution and used in a wet spinning technique for making polymer fibers.

In fact, the primary Vacanti et al. reference is directed to fibrous or polymeric matrices (column 2, lines 66-67) that may include bioactive agents (column 5, lines 45-49). Vacanti et al. neither teaches nor suggests a wet spinning technique, which the Examiner acknowledges (page 4, paragraph 1 of the instant Office Action). Importantly, Vacanti et al.'s fibrous or polymeric *matrix* is described as being "porous." Col. 2 lines 65-67. One of ordinary skill in the art, then, would be led to believe that the bioactive agents of Vacanti et al. occupy the pores or interstitial

sites of the fibrous or polymer matrix and are not formed within the polymer fibers themselves. See also col. 6 lines 14-24 describing bioactive agents within the matrix.

The wet spinning process of the secondary Martin et al. reference described at col. 10 and with reference to Fig. 4 includes combining two different solvent/polymer mixtures and then extruding the combined solvent/polymer mixture into a tank where the mixture then coagulates to form polymer fibers (column 10, lines 39-56). Martin provides no disclosure of incorporating bioactive agents into fibers during fiber formation using an emulsion method as claimed, i.e. immersing an emulsion including the bioactive agent and the polymer into a second solvent, to disperse the bioactive agent homogenously within the fiber.

The Examiner has concluded that one would be motivated to arrive at Applicants' claimed invention because of the beneficial effects of active ingredients released into tissue sites. This rationale, however, does not address the failure of the cited art to teach incorporation of the bioactive agent into the fiber during fiber formation using an emulsion technique. The failure of the cited art to teach use of an emulsion alone should render the claims patentable. However, the specification clearly discloses that the use of the claimed emulsion technique provides beneficial advantages insofar as the bioactive materials are an integrated part of the polymer fiber (specification, page 2, lines 8-10) and are homogenously distribute into the polymers (page 2, lines 31-33). Figure 3 shows desirable release rates for fiber mesh where the active ingredient was included into the fiber during fiber formation as claimed.

The Examiner has not challenged Applicants' disclosure of the claimed process or the advantages of the resulting fiber product as being unbelievable, and in the absence of such a challenge, the Examiner should accept the disclosure as factually true. The claimed technique, therefore, would produce polymer fibers having a very different nature and composition

compared to a polymer fiber lacking bioactive agents. The release of bioactive agents from polymer fibers where the bioactive agents are homogenously within the fiber occurs by a different mechanism and different release kinetics as compared to polymer fibers lacking a bioactive agent, but are used to form a matrix where bioactive materials are added post production to pores and interstitial sites in the matrix. Even if the release kinetics are the same, applicants' method produces a fiber very different in composition and method of release of bioactive agent compared to the fibers made without the emulsion technique including the bioactive agent and relying on release from pores sites within the matrix formed by the fibers.

Having addressed all outstanding issues, Applicants respectfully request reconsideration and allowance of the case. To the extent the Examiner believes that it would facilitate allowance of the case, the Examiner is requested to telephone the undersigned at the number below.

Respectfully submitted,

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